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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

ASTRAZNECA AB, ASTRAZENECA LP, KBI-E INC., and POZEN, INC., Plaintiffs, v. ANCHEN PHARMACEUTICALS, INC., Defendant.	Civil Action No. 3:11-cv-06348-JAP-DEA (Consolidated for discovery purposes with Civil Action Nos. 3:11-cv-02317-JAP-DEA and 3:11-cv-04275-JAP-DEA)

PLAINTIFFS' OPENING *MARKMAN* SUBMISSION

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I. BACKGROUND

A. Overview

Plaintiffs AstraZeneca AB; AstraZeneca LP; KBI-E Inc. (collectively, "AstraZeneca"); and Pozen Inc. ("Pozen"), (collectively, "Plaintiffs") respectfully submit their Opening *Markman* Submission. This is a Hatch–Waxman patent infringement action. AstraZeneca asserts that Defendant Anchen Pharmaceuticals, Inc. infringes four patents related to AstraZeneca's drug product Vimovo®. The patents-in-suit are U.S. Patent Nos. 6,926,907; 6,369,085; 7,411,070; and 7,745,466.

AstraZeneca holds approved New Drug Application No. 022511 for Vimovo®. Vimovo® is a combination drug product, which contains the active ingredients naproxen (a non-steroidal anti-inflammatory drug, or "NSAID") and esomeprazole magnesium trihydrate (a proton-pump inhibitor, or "PPI"). Vimovo® is indicated to relieve the signs and symptoms of osteoarthritis, rheumatoid arthritis, and ankylosing spondylitis, while decreasing the risk of developing gastric ulcers in patients at risk of developing NSAID-associated gastric ulcers. The esomeprazole magnesium trihydrate in Vimovo® is the same active ingredient as that in AstraZeneca's Nexium® (used to treat gastrointestinal disorders).

B. Vimovo®

When combined in Vimovo®, naproxen acts as a pain reliever and inflammation reducer, while esomeprazole magnesium decreases the risk of developing stomach ulcers, a common side effect of long-term, daily NSAID use. Vimovo®'s effectiveness not only results from the combination of naproxen and esomeprazole magnesium in a single tablet, but also from the particular way the two drugs are released from the tablet in the body.

Sufferers of chronic pain often take daily doses of NSAIDs for pain relief. But NSAIDs tend to weaken the mucosal lining of the stomach, and with long-term, daily use, that damage

can lead to the development of stomach ulcers. Because PPIs can reduce the amount of acid in the stomach, many researchers believed that PPIs could reduce the occurrence of stomach ulcers in patients taking long-term, daily doses of NSAIDs. As a result, there were efforts to combine NSAIDs with PPIs, but those efforts failed to develop an effective combination product. Then, in the early 2000s, Dr. John Plachetka, the founder of Pozen, invented a better way to combine NSAIDs, like naproxen, with acid inhibitors, like esomeprazole magnesium. Dr. Plachetka's invention ensures the coordinated delivery of the two drugs and reduces the side effects previously associated with long-term, daily use of NSAIDs alone.

Prior to Dr. Plachetka's invention, it was widely believed that PPIs ***required*** an enteric coating to delay the release of the PPI until after it had passed through the stomach; otherwise, the PPI, which is acid-labile, would be destroyed by the acid in the stomach. But, among other things, the delayed release of enteric coated PPI precluded the coordinated delivery of combined dosages of PPI and NSAID, potentially exposing the stomach to NSAIDs before the onset of PPI activity.

Despite the industry-wide belief that PPIs must be enteric coated, Dr. Plachetka's tablet contained an NSAID core surrounded by an outer layer of PPI that was not enteric coated. Without an enteric coating, the PPI would be immediately released from the tablet into the stomach. Dr. Plachetka also included a delayed release coating between the NSAID core and the outer PPI layer. The delayed release coating would prevent release of the NSAID in the stomach until the amount of acid there had been reduced to safe levels by the PPI. Dr. Plachetka believed the combination of the immediate-release PPI and the delayed release NSAID would reduce the occurrence of stomach ulcers associated with the long-term use of NSAIDs.

Pozen undertook clinical studies to prove that Dr. Plachetka's invention safely and effectively reduces the occurrence of stomach ulcers associated with NSAID use, which led to a partnership with AstraZeneca in 2006 to commercialize Vimovo®.

II. LEGAL PRINCIPLES OF CLAIM CONSTRUCTION

Claim construction is a matter of law for the court. *Cybor Corp. v. FAS Techs., Inc.*, 138 F.3d 1448, 1455–56 (Fed. Cir. 1998); *see also Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 372 (1996). Claim construction focuses on what a person of ordinary skill in the art would have understood a given claim term to mean at the time of the invention. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1313 (Fed. Cir. 2005). The terms of a claim are generally given their ordinary and customary meaning in the art as of the filing date. *See id.* at 1313–14.

In construing claims, a court first looks to the "intrinsic evidence"—the words of the claims themselves, the specification, and the prosecution history. *Phillips*, 415 F.3d at 1313–17. "[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms," *Phillips*, 415 F.3d at 1314; a construction that stays true to the claim language is the correct construction, *Renishaw PLC v. Marposs Societá Per Azioni*, 158 F.3d 1243, 1250 (Fed. Cir. 1998).

The specification and prosecution history provide further guidance for construing claims. *See Phillips*, 415 F.3d at 1315. The specification is "always highly relevant to the claim construction analysis" and is "the single best guide to the meaning of a disputed term." *Id.* (internal quotation marks and citation omitted). Additionally, the prosecution history "can often inform the meaning of the claim language." *Id.* at 1317.

Although the intrinsic evidence is more significant, extrinsic evidence may also be useful in construing claims. Extrinsic evidence includes dictionaries, treatises, and testimony of an inventor or expert witness. *Phillips*, 415 F.3d at 1318. Extrinsic evidence in the form of expert

testimony may be useful "for a variety of purposes, such as to provide background on the technology at issue, to explain how an invention works, to ensure that the court's understanding of the technical aspects of the patent is consistent with that of a person of skill in the art, or to establish that a particular term in the patent or the prior art has a particular meaning in the pertinent field." *Id*. at 1318. However, expert testimony that is conclusory, or clearly at odds with the intrinsic evidence, should be discounted. *See id.* at 1318.

III. CONSTRUCTION OF DISPUTED CLAIM LANGUAGE

Each disputed term is addressed in turn below. AstraZeneca's proposed constructions are consistent with the intrinsic and extrinsic evidence. Defendants' constructions are not.

A. '907 Patent Claim Language in Dispute

The '907 Patent relates to a pharmaceutical composition combining an acid inhibitor, such as the proton pump inhibitor ("PPI") described and claimed in the other patents-in-suit, with a non-steroidal anti-inflammatory drug ("NSAID"). The asserted claims[1] require the coordinated release of the two active ingredients: the acid inhibitor is released first, immediately and regardless of the pH of the surrounding medium, and the NSAID is released second, and only where the pH of the surrounding medium is above a particular level. Through the coordinated release of the two active ingredients, the potential NSAID-related injury can be avoided. *See* Declaration of Erica N. Andersen ("Andersen Decl."), Ex. 1, Abstract; col.3 ll.63–col.4 ll.2.[2]

[1] Plaintiffs are asserting claims 5, 15, 52, 53, and 54.

[2] Unless otherwise specified, all Exhibits are attached to the Declaration of Erica N. Andersen ("Andersen Decl."), accompanying this brief.

The parties dispute the construction of five terms in the asserted claims of the '907 Patent. All are found in claim 1.[3] Claim 1, with the disputed terms bolded and/or italicized, reads:

> 1. A pharmaceutical composition in unit dosage form suitable for oral administration to a patient, comprising:
>
> (a) **an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one or more of said unit dosage forms**;
>
> (b) a non-steroidal anti-inflammatory drug (NSAID) in an amount effective to reduce or eliminate pain or inflammation in said patient upon administration of one or more of said unit dosage forms;
>
> and **wherein said unit dosage form provides for coordinated release** such that:
>
> i) said NSAID is surrounded by **a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher**
>
> ii) **at least a portion of said acid inhibitor is not surrounded by an *enteric coating* and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5**.

1. "an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5 upon the administration of one *or more of said unit dosage forms*"

Plaintiffs' Proposed Construction	Anchen's Proposed Construction
an acid inhibitor present in an amount capable of raising the gastric pH of said patient to at least 3.5 upon the administration of one or more single entities for drug administration over a period of time	an acid inhibitor is present in the unit dosage form in an amount effective to raise the gastric pH to at least 3.5 ***at the time the unit dosage form is administered***

[3] Although claim 1 is not asserted in this litigation, all of the asserted claims depend from claim 1. The asserted claims therefore include each limitation of independent claim 1.

Plaintiffs submit that this phrase should be construed as a person of ordinary skill in the art would understand it: that an "effective amount" of acid inhibitor includes amounts of acid inhibitor that are effective upon administration of "one or more" unit dosage forms, including amounts of acid inhibitor that are effective after administration of ***more than one dosage form*** over time. That understanding takes into account not only the express language of the claims and specification, but also the mechanisms of action of acid inhibitors such as PPIs and how these drugs are typically prescribed. In contrast, Anchen's construction ignores both the intrinsic and extrinsic evidence in an effort to improperly narrow the claims by: (1) limiting the claim to administration of a single unit dosage form, and (2) requiring the acid inhibitor to be effective "at the time" of administration.

Intrinsic Evidence: The disputed claim language itself expressly states that the desired effect, raising the gastric pH to at least 3.5, occurs upon the administration of "one ***or more***" unit dosage forms. In other words, the disputed claim language encompasses pharmaceutical compositions that may require multiple administrations before the amounts of acid inhibitor are effective to raise the gastric pH to the desired level. The claims do not include any further limiting language requiring the "one or more" unit dosage forms to be administered at the same time. Nonetheless, Anchen's proposed construction improperly strikes the "or more" language from the claims and instead requires that the amount of acid inhibitor be effective "at the time" a single unit dosage form is administered. Anchen's efforts to limit the claim by reading out the "or more" language should be rejected. *See Exxon Chem. Patents, Inc. v. Lubrizol Corp.*, 64 F.3d 1553, 1557 (Fed. Cir. 1995) ("We must give meaning to all the words in [the] claims."); *see also Bicon, Inc. v. Straumann Co.*, 441 F.3d 945, 950 (Fed. Cir. 2006) ("[C]laims are interpreted with an eye toward giving effect to all terms in the claim.").

The choice of language in other parts of claim 1 demonstrates that the patentee deliberately included the "one or more" language that Anchen now seeks to strike from the claims. Namely, while clauses (a) and (b) focus on the effect of ***one or more*** unit dosage forms, clauses (i) and (ii) focus on the coordinated release of ***each*** dosage form. More specifically, clauses (a) and (b) of claim 1 refer to the effective amounts of the two active ingredients and include the "one or more" language to describe how many unit dosage forms may be required to achieve the claimed effects. By contrast, clauses (i) and (ii), which relate to aspects of the unit dosage form's coordinated release, do not use the "one or more" language and state only that the claimed release occurs "upon ingestion of said unit dosage form." While the claimed type of release (either delayed or immediate) must occur "upon ingestion" of ***each*** unit dosage form, the effects of the acid inhibitor and NSAID may occur "upon administration of ***one or more***" unit dosage forms. *See Phillips*, 415 F.3d at 1314 ("[T]he claims themselves provide substantial guidance as to the meaning of particular claim terms.").

The specification also explains why the claims include amounts of acid inhibitors that may not be effective until after the administration of more than one dose. The specification explains that in contrast to other acid inhibitors, such H_2 receptor antagonists, a PPI's,[4] "antisecretory effect may be delayed for several hours and ***may not take full effect for several days***." Andersen Decl., Ex. 1, col.1 ll.62–63 (emphasis added). As discussed below, this statement reflects the understanding of one of skill in the art, *i.e.*, that PPIs often require repeated administration over several days to reach effective steady-state acid inhibition. *See* Declaration of Dr. David A. Johnson ("Johnson Decl.") at ¶¶ 29–35.

[4] Although claim 1 is directed to an "acid inhibitor," the asserted claims depend from claim 1 and require the acid inhibitor to be a PPI. Thus, the effective amount of acid inhibitor in claim 1, must include effective amounts of PPIs.

Indeed, as PPIs may require repeated administration over several days to become effective, Anchen's construction would exclude preferred embodiments from the claims. For example, the specification states that 20 mg of omeprazole is a preferred amount of omeprazole. Andersen Decl., Ex. 1, col.7 ll.9–11. But that dosage generally requires several days of administration to become effective. *See* Johnson Decl. at ¶ 39. Because constructions that exclude preferred embodiments are "rarely, if ever, correct," Anchen's attempt to improperly limit the claims should be rejected. *See Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1583–84 (Fed. Cir. 1996).

Extrinsic Evidence: Claims must be interpreted in view of the knowledge of one of ordinary skill in the art. *Apex Inc. v. Raritan Computer, Inc*., 325 F.3d 1364, 1373 (Fed. Cir. 2003) (citing *Vitronics*, 90 F.3d at 1582). Here, a person of ordinary skill in the art would have understood that PPIs, such as those recited in the claims of the '907 Patent, typically require repeated administration over several days to reach steady-state acid inhibition. *See* Johnson Decl. at ¶¶ 29–35. Those of skill in the art would also have understood the physiological basis for this characteristic: each dose of PPI is only capable of inhibiting a fraction of the acid-producing proton pumps in the stomach, and therefore several doses of PPI over several days may be required to inhibit enough proton pumps to reach steady state acid inhibition. *Id.* These facts are widely reported in the literature. *See, e.g.*, Andersen Decl., Ex. 2, at 66; *id.*, Ex. 3, at 144–45; *id.*, Ex. 4 at 965. Because those of skill in the art would understand that PPIs typically require repeated administration over several days to become effective, they would have understood the disputed claim language—which refers to the administration of one or more unit dosage forms—to include amounts of acid inhibitors that may require multiple doses over time to raise the gastric pH to 3.5. *See* Johnson Decl. at ¶¶ 36–38.

2. "wherein said unit dosage form provides for coordinated release"

Plaintiffs' Proposed Construction	Anchen's Proposed Construction
wherein the single entity for drug administration provides for the sequential release of acid inhibitor followed by NSAID	release of the NSAID in the unit dosage form is prevented ***until the acid inhibitor in the unit dosage form increases gastric*** pH to at least 3.5

The specification of the '907 Patent provides a definition for the term "coordinated release": the sequential release of acid inhibitor followed by NSAID. Plaintiffs stand by that definition. Anchen's construction, however, deviates from it to require that the acid inhibitor raise the gastric pH before NSAID is released. As a result, Anchen's construction excludes a preferred embodiment from the claims and should therefore be rejected.

Intrinsic Evidence: When the patentee defines a claim term in the specification, that definition provides the correct construction for the term. *Phillips*, 415 F.3d at 1321 ("[T]he specification acts as a dictionary when it expressly defines terms used in the claims . . . .") (internal quotation marks omitted); *see also Honeywell Int'l, Inc. v. Univ. Avionics Sys. Corp.*, 493 F.3d 1358, 1361 (Fed. Cir. 2007) ("When a patentee defines a claim term, the patentee's definition governs, even if it is contrary to the conventional meaning of the term."). Here, the specification of the '907 Patent provides an express definition for the term "coordinated release:"

> All of the dosage forms are designed for oral delivery and provide for the ***coordinated release of therapeutic agents, i.e., for the sequential release of acid inhibitor followed by analgesic***.

Andersen Decl., Ex. 1, col.5 ll.16–20 (emphasis added). The use of "*i.e.*" in this passage indicates the patentee's intent to define "coordinated release" to mean "the sequential release of acid inhibitor followed by [NSAID]." *See Edwards Lifesciences LLC v. Cook Inc.*, 582 F.3d 1322, 1334 (Fed. Cir. 2009) ("[T]he specification's use of '*i.e.*' signals an intent to define the word to which it refers . . . ."). Thus, that definition governs.

The definition in the specification is also consistent with the claims, the rest of the specification, and the prosecution history. Claim 1 requires the acid inhibitor to release "upon ingestion" regardless of the surrounding pH, while NSAID release is prevented unless the pH of the surrounding medium—whether it be in the stomach or intestines—is 3.5 or higher. The specification similarly indicates that the dosage form "provides for coordinated release . . . *i.e.*, the acid inhibitor is released first and the release of NSAID is delayed until after the pH in the ***GI tract*** has risen." Andersen Decl., Ex. 1, col.3 l.63–col.4 l.2. The examples in the specification likewise repeatedly explain that the acid inhibitor is immediately released from the dosage form, while the NSAID's release is delayed until the dosage form reaches an environment with a safe pH. *See, e.g.*, *id.* at col.8 ll.35–49; col.9 ll.50–62. And during prosecution, the patentee repeatedly characterized the claims as requiring "coordinated sequential delivery" or "the coordinated delivery of acid inhibitor followed by NSAID," and, finally, that "acid inhibitor release from Applicant's compositions is immediate and only the release of the NSAID is delayed." Andersen Decl., Ex. 5, at 3, 5; *see also id.*, Ex. 6.

Anchen's construction, however, sets aside the definition in the specification to instead require that NSAID release is prevented "until the acid inhibitor increases gastric pH to at least 3.5." Practically, Anchen seeks to limit the release of the NSAID to only one part of the GI tract—the stomach—and only after the acid inhibitor has become effective. Anchen's construction ignores the claim language and improperly excludes preferred embodiments of the '907 Patent. As explained above, PPIs typically require repeated administration over several days before becoming effective and raising the gastric pH to the desired level. The claims reflect this characteristic and specify that the NSAID release is prevented unless the pH of the "***surrounding medium***" is 3.5 or higher, indicating that NSAID release may occur in the

intestinal medium if the stomach pH is not raised. The claims do ***not*** require that the "surrounding medium" be gastric, as Anchen's construction would require. Indeed, when the patentee wanted to refer to the "gastric pH," the patentee did so explicitly, for example, in clause (a) of claim 1 (describing the amount of acid inhibitor in the composition).

The specification also repeatedly explains that in a situation where the gastric pH has not been raised, the NSAID would not release "in an unprotected stomach," but instead would release when the dosage form "reaches an environment where the pH is above about 4." Andersen Decl., Ex. 1, col.14 ll.59–65; *see also, e.g., id.* col.13 ll.12–18. Because the pH of the gastrointestinal tract increases to more than 5 in the small intestine, a dosage form that passes through an "unprotected stomach," *i.e.*, before the PPI has increased the gastric pH, would still release in the higher pH environment of the small intestine. *See* Williams Decl. at ¶¶ 32, 34; *see also* Andersen Decl., Ex. 7, at 107 (stomach is pH 1–3, while small intestine is pH 5–7). Thus, Anchen's construction essentially seeks to exclude compositions containing PPIs from the claims, even though PPIs are an expressly claimed and preferred embodiment. *Vitronics*, 90 F.3d at 1583–84. Anchen's construction should therefore be rejected.

Extrinsic Evidence: Plaintiffs' construction of the claim term is also consistent with the meaning one of ordinary skill in the art would attribute to that term in view of the definition in the specification. One of ordinary skill would understand that the specification defines "coordinated release" to mean "sequential release of acid inhibitor followed by NSAID." Williams Decl. ¶¶ 29–31.

3. "a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher"

Plaintiffs' Proposed Construction	Anchen's Proposed Construction
No construction is needed. This phrase	A coating that, upon ingestion of said unit dosage

should be given its plain and ordinary meaning.	form by said patient, controls the release of NSAID ***by time or pH*** and thereby prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher

AstraZeneca and Pozen submit that this phrase should be given its customary and ordinary meaning. In other words, this phrase means exactly what it states—that the coating prevents release of the NSAID unless the pH of the surrounding medium is 3.5 or higher, and thus the coating controls release by pH only. In contrast, Anchen's construction ignores the plain language of the claim and broadens the claim to include coatings that control release by either time or pH.

Intrinsic Evidence: The plain language of claim 1 requires that the coating controls the release of the NSAID by pH rather than by time. Each of the independent claims of the '907 Patent covers one of the two alternative embodiments of the invention—either a time-dependent or a pH-dependent embodiment. Claim 1 covers the pH-dependent embodiment, while independent claim 37 covers the time-dependent embodiment. Claim 1 states that the coating prevents the release of the NSAID "***unless the pH of the surrounding medium is 3.5 or higher***." Thus, the ***only*** claimed form of control for NSAID release in claim 1 is by pH; that is, the NSAID cannot be released "unless" the pH is 3.5 or higher. There is absolutely no claim language directed to controlling the release of the NSAID by time. By contrast, claim 37 requires a coating "that dissolves ***at a rate*** such that said NSAID is not released until said gastric pH is at 3.5 or higher," indicating that the NSAID release in claim 37 depends on time. Had the patentee contemplated claiming time-controlled NSAID release in claim 1, the patentee could have expressly included similar language to that in claim 37. However, the patentee chose to draft claim 1 by omitting language specifying a time-dependent release of the NSAID. As the

Federal Circuit has explained, "a construction that flies in the face of the express language of the claim is not preferred." *Telemac Cellular Corp. v. Topp Telecom, Inc.*, 247 F.3d 1316, 1324 (Fed. Cir. 2001) (rejecting proposed construction of claim language relating to communications established by a host processor as also including communications established by the user); *see also Phillips*, 415 F.3d at 1312 ("It is a bedrock principle of patent law that the claims of a patent define the invention to which the patentee is entitled the right to exclude.") (internal quotation marks omitted). Consequently, the asserted claims—by their own terms—cannot be construed as encompassing control of NSAID release by ***either*** time ***or*** pH as Anchen proposes.

The specification and the prosecution history confirm that this claim term should be given its plain and ordinary meaning, and that no further construction is necessary. Mirroring claims 1 and 37, the specification of the '907 Patent discloses two ***alternative*** embodiments relating to NSAID release. The specification makes clear that these two embodiments are different, and that claim 1 is drawn to ***only one*** of these two alternatives. The specification describes coatings that dissolve based on the pH of the surrounding medium, as well as ***different*** coatings that control the release of NSAID based on time:

> In the most preferred form, coordinated delivery is accomplished by having the inner core surrounded by a polymeric barrier coating ***that does not dissolve unless the surrounding medium is at a pH of at least 3.5***, preferably at least 4 and more preferably, at least 5. ***Alternatively, a barrier coating may be employed which controls the release of NSAID by time***, as opposed to pH, with the rate adjusted so that NSAID is not released until after the pH of the gastrointestinal tract has risen to at least 3.5, preferably at least 4, and more preferably at least 5. Thus, a time-release formulation may be used to prevent the gastric presence of NSAID until mucosal tissue is no longer exposed to the damage enhancing effect of very low pH.

Andersen Decl., Ex. 1, col.4 ll.5–17 (emphases added); *see also id*. at col.4 ll.32–38.

Claim 1 incorporates the ***exact*** language from the specification regarding pH-dependent release, but notably does ***not*** include the language about the ***alternative*** coatings that control the release by time, which are specifically claimed in unasserted claim 37. Consequently, although the specification describes two different types of NSAID coatings, claim 1 covers only pH-dependent coatings. That claim 1 does not cover both of the NSAID coating embodiments disclosed in the specification is of no moment. The Federal Circuit has explained that "a claim need not cover all embodiments . . . . A patentee may draft different claims to cover different embodiments." *Intamin Ltd. v. Magnetar Techs. Corp.*, 483 F.3d 1328, 1337–38 (Fed. Cir. 2007) (internal citations omitted).

The prosecution history also supports Plaintiffs' construction. Specifically, the prosecution history reveals that claim 1 was limited by amendment to include only pH-controlled NSAID coating. As originally filed, claim 1 did not require an NSAID coating at all. *See* Andersen Decl., Ex. 8, at 30. In the final amendment before the Examiner allowed the claims, however, the patentee added the now-disputed phrase to claim 1. This amendment introduced the limitation that the pharmaceutical composition include "***a coating that . . . prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher***." *See* Andersen Decl., Ex. 6, at 2 (emphasis added). Consequently, the amendment limited the scope of claim 1 to a pharmaceutical composition comprising the pH-controlled NSAID coating described in the specification. Because the patentee deliberately chose ***not*** to claim a time-controlled NSAID coating in claim 1, claim 1 should not be construed to include that embodiment. *See Sinorgchem Co. v. Int'l Trade Comm'n*, 511 F.3d 1132, 1138–39 (Fed. Cir. 2007) ("Where, as here, multiple embodiments are disclosed, we have previously

interpreted claims to exclude embodiments where those embodiments are inconsistent with unambiguous language in the patent's specification or prosecution history.").

Extrinsic Evidence: Plaintiffs' construction of the claim term is consistent with how one of ordinary skill in the art would understand the phrase. In other words, to a person of ordinary skill in the art, the plain language of the phrase itself sets out that release of the NSAID is controlled by pH, rather than by pH or time as Anchen asserts. Williams Decl. ¶¶ 35–36.

In summary, Anchen's proposed construction is contrary to the plain meaning of the claim language, ignores the language of the specification, and improperly expands the definition of the NSAID coating to include an embodiment that was specifically excluded from the claim during prosecution. The phrase should be construed exactly as it is written—as a coating that, upon ingestion of said unit dosage form by said patient, prevents the release of essentially any NSAID from said dosage form unless the pH of the surrounding medium is 3.5 or higher.

4. "enteric coating"

Plaintiffs' Proposed Construction	Anchen's Proposed Construction
a delayed release coating	a coating that controls the release of an active agent from a unit dosage form ***by pH***

Plaintiffs submit that the term "enteric coating" should be construed as one of skill would understand it in view of the claims, the specification, and the prosecution history: a delayed-release coating. In contrast, Anchen's construction seeks to import a limitation into the claims by limiting the enteric coating to one that controls the release of an active ingredient from a unit dosage form only "by pH." Because there is no legitimate basis to import this limitation into the claims, the Court should reject Anchen's proposed construction.

Intrinsic Evidence: Generally, the term "enteric" broadly refers to the location of the gastrointestinal tract that is after the stomach, *i.e.*, the intestine. *See, e.g.*, Andersen Decl., Ex. 1,

col.1 l.64–col.2 l.2 ("[T]his class of drugs is enteric coated to avoid destruction by stomach acid."); *id.* at col.9 ll.50–57 ("The function of the enteric coat is to delay the release of naproxen . . . . The coating does not dissolve in the harshly acidic pH of the unprotected stomach."). In other words, the term "enteric" would be understood by a person of ordinary skill in the art as a coating that delays dissolution of the coating and release of the drug, but does not limit the manner in which the drug release is delayed. Anchen's construction is inappropriately limiting, because, while pH is ***one way*** of controlling and delaying drug release, it is not the ***only way.***

The language of the claims establishes that "enteric coating" has its plain and ordinary meaning, and thus a broader meaning than a coating that controls release of an active ingredient only "by pH" as Anchen proposes. The relevant portion of claim 1 states:

> at least a portion of said acid inhibitor is not surrounded by an ***enteric coating*** and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5.

This phrase not only requires that (1) at least some of the acid inhibitor is not enteric coated, but also further requires that (2) the non-enteric coated acid inhibitor releases irrespective of pH. If an enteric coating is a coating that dissolves based on pH alone, as Anchen contends, the language requiring that the acid inhibitor release irrespective of pH would render the "enteric coating" limitation superfluous. Using Anchen's proposed construction, the claim would read:

> at least a portion of said acid inhibitor is ***not surrounded by a coating that controls the release of an active agent from a unit dosage form by pH*** and, upon ingestion of said unit dosage form by said patient, ***is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5***.

An acid inhibitor ***lacking*** a coating that prevents release by pH ***would by definition release irrespective of pH***, and in view of the limitation already requiring that the acid inhibitor be released regardless of pH, would be superfluous. *See Exxon Chem. Patents*, 64 F.3d at 1557

(explaining that claims may not be construed in a manner that renders a claim term meaningless or superfluous).

The specification likewise demonstrates that the term "enteric coating" is not a term reserved for pH-dependent coatings. In the background section of the specification, for example, the patentee refers to "[t]he addition of a ***pH sensitive enteric coating*** to an NSAID." *See* Andersen Decl., Ex. 1, col.2 ll.2–13 (emphasis added). If enteric coatings were, by definition, pH-sensitive, it would be meaningless for the patentee to specify that one particular enteric coating is "pH sensitive." *See Phillips*, 415 F.3d at 1312–13 (explaining that the term "steel baffles" in the claims "strongly implies" that the term "baffles" is not inherently limited to being made of steel). And, consistent with AstraZeneca and Pozen's proposed construction, the specification also repeatedly describes enteric coatings as coatings used to delay the release of drug. *See* Andersen Decl., Ex. 1, col.9 ll.50–52; col.10 ll.57–58; col.11 l.67–col.12 l.1 ("The function of the enteric coat is to delay the release of naproxen."); *id*. at col.16 ll.32–33 ("The release of naproxen sodium is delayed by enteric coating.").

Finally, the prosecution history also confirms that the claim language "enteric coating" is not limited to coatings that control release by pH. During prosecution, the patentee described enteric coatings as coatings that delay release of a drug, and relied on this feature to distinguish the claims over the prior art. The Examiner rejected the pending claims as anticipated by a patent allegedly disclosing an enteric-coated acid inhibitor (PPI).[5] At the time, claim 1 recited "an acid inhibitor present in an amount effective to raise the gastric pH of said patient to at least 3.5," and did not indicate that at least a portion of the acid inhibitor is not surrounded by an enteric coating. *See* Andersen Decl., Ex. 9, at 3. To overcome the rejection, the patentee

[5] Depui (U.S. Patent No. 6,613,354).

amended pending claim 1 to exclude an enteric coating on at least a portion of the acid inhibitor (PPI)[6] and emphasized that in the prior art, the acid inhibitors were enteric coated, and drug release "would be ***delayed*** whereas acid inhibitor release from Applicant's compositions is immediate." *See* Andersen Decl., Ex. 6, at 2, 11–12 (emphasis added). The Examiner then allowed the claims. Thus, the Applicant broadly categorized the enteric-release coatings of the prior art as delayed release coatings, and the Examiner accepted this definition.

Extrinsic Evidence: A skilled person in the art at the time of the invention would not understand the term "enteric coating" to be limited to a pH-dependent coating. Williams Decl. ¶¶ 43–46. Rather, a skilled person would understand "enteric coating" to mean a delayed release coating, typically used to delay release of a drug until it reaches the intestines. *Id*. Indeed, around the time of the invention, the Food and Drug Administration ("FDA") characterized enteric coatings as "[i]ntended to delay the release of the drug (or drugs) until the dosage form has passed through the stomach" and "delayed release dosage forms." *Id*. at ¶¶ 43–44.[7] Dr. John Horn—the expert for Dr. Reddy's and Lupin in the consolidated cases—agreed that FDA's definition is "correct" and would be "as good as anybody else's definition." Andersen Decl., Ex. 30, at 78:21–79:1; 84:8–24.

As Dr. Williams explains, one skilled in the art would know of a variety of mechanisms by which enteric coatings can delay release of a drug until it reaches the intestines. Williams Decl. ¶ 45. Some enteric coatings delay release by using pH-dependent polymers that only

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[6] The patentee amended the claims to include the phrase of issued claim 1 stating that, "at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5." *See* Andersen Decl., Ex. 6, at 2.

[7] The FDA document relied upon by Dr. Williams is dated September 1997, and was therefore available at the time of the invention.

dissolve above a pre-determined pH threshold. *Id.* Other types of enteric coatings are formulated to release after a pre-determined amount of time. *Id.* More recently, enteric coatings have been designed that release in the intestines using bacteria that break down the coating to release the drug. *Id.*

In sum, Anchen's proposed construction attempts to improperly limit the definition of "enteric coating" to just one type of enteric coating—a pH-sensitive coating. But the intrinsic record offers no legitimate basis to depart from the plain and ordinary meaning that "enteric coating" would have to those of skill in the art. *See Thorner v. Sony Computer Entm't Am. LLC*, 669 F.3d 1362 (Fed. Cir. 2012) ("only two exceptions" to the plain and ordinary meaning of claim term are when the patentee acts as its own lexicographer, or disavows the full scope of the claim term in the specification or during prosecution). Indeed, Anchen's proposed construction runs contrary to the description in the specification and statements in the prosecution history. Consequently, "enteric coating" should not be limited to just one type of enteric coating, but should be given its full meaning—a coating that delays release of a drug.

5. "at least a portion of said acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5"

Plaintiffs' Proposed Construction	Anchen's Proposed Construction
This phrase should be given its plain and ordinary meaning. The plain and ordinary meaning is: At least a portion of said proton pump inhibitor is immediately released	At least some amount of acid inhibitor is not surrounded by an enteric coating and, upon ingestion of said unit dosage form by said patient, is released regardless of whether the pH of the surrounding medium is below 3.5 or above 3.5

Plaintiffs apparently agree with Anchen—whose construction largely tracks the disputed phrase—that this phrase should be given its plain and ordinary meaning. Anchen, however, has

not articulated how the plain and ordinary meaning deviates from AstraZeneca and Pozen's proposed construction in light of the intrinsic evidence, *i.e.*, that at least a portion of the acid inhibitor is immediately released.

Intrinsic Evidence: The claims themselves require that at least a portion of the acid inhibitor is immediately released. Claim 1 provides that at least a portion of the acid inhibitor is not enteric coated and releases ***upon ingestion*** irrespective of pH. The absence of an enteric coating (a delayed-release coating) results in the acid inhibitor releasing immediately, regardless of the pH the stomach (which may be well below 3.5).

The specification confirms this plain and ordinary meaning. Indeed, the specification repeatedly explains that "[t]he outermost layer [of the dosage form] contains an 'acid inhibitor' in an effective amount which is released from the dosage form ***immediately*** after administration to the patient." *See* Andersen Decl., Ex. 1, col.8 ll.47–49; col.9 ll.60–62; col.10 l.66–col. 11 l.1; col.12 ll.9–11 (emphasis added). Furthermore, every single example of a dosage form in the specification (Examples 1–7) characterizes the acid inhibitor as "immediate release."[8]

Finally, the prosecution history compels a construction requiring immediate release of at least a portion of the acid inhibitor. During prosecution, the patentee added the disputed phrase to claim 1. In their remarks accompanying the amendment, the patentee emphasized that "release from Applicant's [claimed] compositions is ***immediate***." *See* Andersen Decl., Ex. 6, at 2, 11–12 (emphasis added). The claims should not now be construed differently. *See Gillespie*

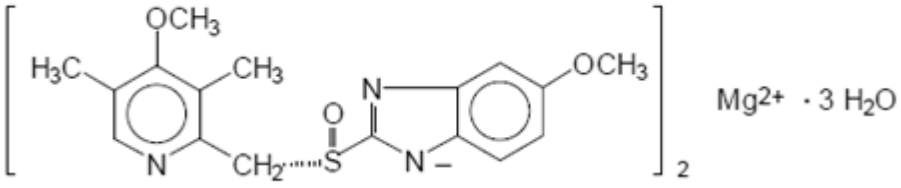
[8] For instance, the dosage form of Example 5 is called "*Enteric Coated Naproxen Sodium Core and Pantoprazole* ***Immediate Release*** *in Film Coat*". *See* Andersen Decl., Ex. 1, col.12 ll.62 (emphasis added). Example 6 is called "*Enteric Coated Naproxen Sodium Core and Omeprazole* ***Immediate Release*** *in Film Coat.*" *Id*. at col.14 ll.41–42 (emphasis added). Example 7 is called "*Naproxen Sodium Delayed Release Omeprazole* ***Immediate Release*** *Capsule.*" *Id*. at col.16 ll.21–22 (emphasis added).

v. Dywidag Sys. Int'l, USA, 501 F.3d 1285, 1291 (Fed. Cir. 2007) (explaining that patentee should be held to "what he declare[d] during the prosecution of his patent"); *Liquid Dynamics Corp. v. Vaughn Co.*, 355 F.3d 1361, 1367–68 (Fed. Cir. 2004) (explaining that patentee's statements made during prosecution can serve to clarify the scope of the term at issue).

Extrinsic Evidence: Plaintiffs' construction of the claim term is also consistent with the meaning one of ordinary skill in the art would attribute to that term. One of ordinary skill would understand that an acid inhibitor lacking an enteric coating (*i.e.*, lacking a delayed release coating) will immediately release into stomach upon ingestion irrespective of pH. Williams Decl. ¶ 48. As Dr. Williams explains, "immediately release" means that the dosage form "[a]llows the drug to dissolve in the gastrointestinal contents, with no intention of delaying or prolonging the dissolution or absorption of the drug." *Id.* at ¶ 49. Dr. Williams bases his understanding of "immediate release" on FDA's definition of the term.[9] *Id.*

B. '085, '070, and '466 Patent Claim Language In Dispute

As stated above, Vimovo® is a combination product containing naproxen and the trihydrate form of esomeprazole magnesium. The structural formula of esomeprazole magnesium trihydrate is:



The '085 and '070 Patents protect the invention of esomeprazole magnesium trihydrate; while the '466 Patent protects the invention of the combination of esomeprazole magnesium

[9] The FDA explains that an immediate release dosage form "[a]llows the drug to dissolve in the gastrointestinal contents, with no intention of delaying or prolonging the dissolution or absorption of the drug."

trihydrate and a second active ingredient, selected from a group that includes NSAIDs. The three patents have the same inventors and specification, but different claims. The '085 Patent issued first, and is limited to a specific form of "the magnesium salt of S-omeprazole trihydrate" characterized by certain x-ray diffraction "d-values." Andersen Decl., Ex. 10, col.10 ll.15–34. The '070 Patent later issued without any restrictions on the characteristics of the claimed esomeprazole magnesium trihydrate. *See* Andersen Decl., Ex. 11, col.10 l.52. The '466 Patent claims pharmaceutical compositions and methods of treatment comprising the esomeprazole magnesium trihydrate (as broadly claimed in the '070 Patent) and a second active ingredient. *See* Andersen Decl., Ex. 12, col.10 ll.50–60. Dr. Stephen Byrn, a leading expert on solid state chemistry, provides a declaration explaining a skilled person's understanding.[10]

1. "magnesium salt of S-omeprazole trihydrate" ('085 Patent, Claims 1–4 and 12; '070 Patent, Claims 1–4; and '466 Patent, Claims 1–5, 7–14, and 16)

Plaintiffs' Proposed Construction	Anchen's Proposed Construction
"magnesium salt" means "a compound formed between positively-charged Magnesium (Mg) cations and negatively-charged esomeprazole anions," and "S-omeprazole trihydrate" means (S)-omeprazole having a structure that has a theoretical ratio of three molecules of bound water per molecule of $((S)\text{-omeprazole})_2$ magnesium, but which does not necessarily contain exactly three molecules of water, whose structure may be determined by analytical methods identified in the patent and known to those of ordinary skill. In '085 patent, the structure is determined by examining XRD.	A trihydrate of a magnesium salt of S-omeprazole containing three molecules of water per molecule of magnesium salt of S-omeprazole in a unit cell of the crystal lattice that is substantially free from magnesium salts of R-omeprazole and other prior art forms of magnesium salts of S-omeprazole including S-omeprazole dihydrate and amorphous forms

The term "magnesium salt of S-omeprazole trihydrate" appears in all asserted claims of the '085, '070, and '466 Patents. AstraZeneca's construction is supported by both the intrinsic

[10] The Declaration of Dr. Byrn is identical to his Declaration submitted in *AstraZeneca AB et al. v. Dr. Reddy's Labs. et al.*, 3:11-cv-02317 (D.N.J) and *AstraZeneca AB et al. v. Lupin Ltd. et al.*, 3:11-cv-04275 (D.N.J.).

and extrinsic evidence. Defendants' construction, on the other hand, incorrectly seeks to import three limitations (crystallinity, purity in terms of the magnesium salt of the R-enantiomer, and purity in terms of other hydrate forms) in a way not contemplated by the patent.

Intrinsic Evidence: The claim language "the magnesium salt of esomeprazole trihydrate" is not further limited in structural form, crystallinity, purity, amount, or concentration of the claimed compound. Claim 1 of the '070 Patent is a compound claim; other claims address preferred embodiments, processes, and pharmaceutical compositions, *see* Andersen Decl., Ex. 10, col.10 l.15–col.12 l.5. The broad scope of the term "the magnesium salt of S-omeprazole trihydrate" is apparent by comparing claim 1 of the '070 Patent to the other claims. Claim 1 of the '070 Patent simply reads "The magnesium salt of S-omeprazole trihydrate." By contrast, claim 1 of the '085 Patent is narrower and addresses a preferred embodiment that "is characterized by the following major peaks in its X-ray diffractogram: [d-value / Å and intensity peak list]." Andersen Decl., Ex. 10, col.10 ll.15–33. Additionally, claim 2 of the '085 Patent further limits claim 1 to the compound "in a highly crystalline form." *Id.* at col.10 ll.34–36. The additional crystallinity limitation in claim 2 shows that the term "the magnesium salt of S-omeprazole trihydrate" does not require any particular level of crystallinity. The claims therefore indicate that the term "the magnesium salt of esomeprazole trihydrate" broadly covers the compound and is not further limited to a particular structural form, degree of crystallinity, purity, or concentration.

The shared specification also makes clear that the term "magnesium salt of S-omeprazole trihydrate" is not limited to any particular form, degree of crystallinity, purity, or amount. The shared specification of these patents states only that the invention relates to a novel form of the (–)-enantiomer of omeprazole—a trihydrate form. *See, e.g.*, Andersen Decl., Ex. 10, col.1 ll.7–

16. As the trihydrate in ***any amount*** was novel at the time of the invention, the term does not require a particular amount, concentration, or purity. The specification also states that the magnesium salt of S-omeprazole occurs in a number of structurally different forms, showing that the phrase "the magnesium salt of S-omeprazole trihydrate" includes all manifestations of that novel trihydrate. *Id.* at col.2 ll.14–15. Furthermore, according to the specification, the magnesium salt of esomeprazole trihydrate can be characterized/identified using different analytical techniques, including FT-IR, which does not require crystallinity for detection and characterization. *See id.* at col.2 ll.38–41, 58–59; col.3 ll.50–56. Thus, the specification does not require "the magnesium salt of S-omeprazole trihydrate" to exist in any minimum amount, level of purity, or level of crystallinity. While the shared specification of the three patents does describe characteristics found in some examples of the compound, these characteristics do not limit the scope of the claimed invention, as expressly stated in the specification. *See* Andersen Decl., Ex. 10, col.2 ll.21–28, 39–42, 47–50, 58–59; *id.* at col.5 ll.4–5; *see also SmithKline Beecham Corp. v. Apotex Corp.*, 403 F.3d 1331, 1352 (Fed. Cir. 2005).

The prosecution history also strongly supports AstraZeneca's construction, and indicates the "magnesium salt of esomeprazole trihydrate" is not further limited to a specific structural form, purity, or concentration. The Langkilde Declaration, submitted during prosecution of the '085 Patent, states that "at the time the claimed invention was made, ***there was no suggestion that the magnesium salt of S-omeprazole existed in a trihydrate form***. It was indeed surprising, therefore, to obtain the claimed compound." *See* Andersen Decl., Ex. 13 (emphasis added). Thus, at the time of the invention, ***any*** amount, purity, or concentration of the compound was novel and inventive. Furthermore, claim 1 of U.S. Application No. 09/077,719 (the "'719 application," the parent application to the application that matured into the '085 Patent) did not

specify or limit the claimed esomeprazole magnesium trihydrate as to structural form, amount, purity, concentration, or crystallinity. *See* Andersen Decl., Ex. 14, at 20. Claim 1 of the '719 application is the same as claim 1 of the issued '070 Patent, while the additional limitations of claim 1 of the '085 Patent were part of dependent claim 3 of the '719 application. *See id.* Thus, the term "the magnesium salt of S-omeprazole trihydrate" (which is also the whole of claim 1 of the '070 Patent), is broadly directed to this compound, and does not require a specific structural form, level of crystallinity, amount, purity, or concentration.

In the prosecution of the '070 Patent, as well, the Examiner acknowledged the instant trihydrate as including, but not limited to, the crystalline form. *See* Andersen Decl., Exs. 15, 16. Further, the Examiner acknowledged that "the magnesium salt of S-omeprazole trihydrate" is not limited to a particular form having a certain XRD pattern. Claims 1 and 2 of the '070 Patent were rejected during prosecution for statutory double patenting, as being the same as '085 Patent claims 1 and 2. *See* Andersen Decl., Ex. 17. AstraZeneca appealed this final rejection, explaining that the '070 Patent claims are different and broader in scope than those in the '085 Patent, and that the prosecution history of both patents supports and is consistent with this position. *See* Andersen Decl., Ex. 18. In response to AstraZeneca's appeal, the Examiner withdrew the final rejection. *See* Andersen Decl., Ex. 19.

Extrinsic Evidence: A skilled person understands that the claim language the "magnesium salt of esomeprazole trihydrate" does not require, specify, or limit as to structural form, extent of crystallinity, amount, purity, or concentration. Declaration of Dr. Stephen R. Byrn ("Byrn Decl.") ¶¶ 16–23. The skilled person understands that a "trihydrate" describes a compound, in theory, having three bound molecules of water per every molecule of the magnesium salt of S-omeprazole (theoretical or stoichiometric ratio). *Id.* ¶ 17 ("[T]he skilled

person would also understand the term hydrate, as used in the term trihydrate, as meaning that the associated water is bound to the molecules of the compound."). "[A] hydrate need not be crystalline to be considered a hydrate, although it must have some structure that can bind water in a regular way. The term hydrate differentiates a compound from other substances in which the water present is loosely associated or only present on the surface." *Id.* Thus, a skilled person would understand that Plaintiffs' construction is correct.

2. "highly crystalline form" ('085 Patent, Claims 2, 4, and 12; '466 Patent, Claims 4 and 12)

Plaintiffs' Proposed Construction	Anchen's Proposed Construction
a form having a repeating pattern of atoms or molecules in an order that can be detected by techniques known in the art, that is more ordered than previously known and disclosed forms	having a crystallinity higher than any other form of magnesium salt of S-omeprazole disclosed in the prior art

The term "highly crystalline form" appears in claims 2, 4, and 12 of the '085 Patent; and claims 4 and 12 of the '466 Patent. The term "crystalline" is understood by skilled persons as having its plain meaning, namely a substance in which the atoms or molecules are arranged in an ordered, repeating pattern. Byrn Decl. ¶¶ 24–25. Plaintiffs submit that intrinsic and extrinsic evidence compel its construction of "highly crystalline form."

Intrinsic Evidence: The specification indicates that the "highly crystalline" compounds of the invention are "characterized by . . . having a higher crystallinity than any other form of magnesium salt of S-omeprazole disclosed in the prior art." Andersen Decl., Ex. 10, col.2 ll.47–50. Thus, "highly" crystalline is a comparative phrase that indicates a more crystalline structure than that of previously known and disclosed forms. *See also* Andersen Decl., Ex. 20.

Extrinsic Evidence: A person skilled in the art would understand the term "crystalline" as meaning a substance in which the atoms or molecules are arranged in an ordered, repeating pattern. *See* Andersen Decl., Exs. 21–22. Dr. Byrn explains that crystallinity in the context of

"highly crystalline" permits a mixture of crystalline and amorphous material—the phrase is comparative and merely indicates that the crystalline portion is more ordered than those in the prior art. *See* Byrn Decl. ¶¶ 24–25; *see also* Andersen Decl., Exs. 23–26. As Dr. Byrn explains, a person of ordinary skill in the art understands crystallinity in terms of the order of the atoms or molecules of a material. Plaintiffs' construction accounts for this understanding.

3. "characterized by the following major peaks in its X-ray diffractogram" ('085 Patent, Claims 1–4, and 12; '466 Patent, Claims 3 and 11)

Plaintiffs' Proposed Construction	Anchen's Proposed Construction
identifiable by reference to an X-ray diffractogram that includes the major peaks below	having all of the referenced major peaks in its X-ray diffractogram

The claim language "characterized by the following major peaks in its X-ray diffractogram" should be construed to mean "identifiable by reference to an X-ray diffractogram that includes the major peaks below," as "characterized" is an inclusive transitional phrase, and the listed "peaks" must be sufficient to distinguish or identify the specific trihydrate form claimed. The intrinsic evidence makes clear that the X-ray diffractogram for the claimed S-omeprazole trihydrate need not have "all" of the referenced major peaks, as Anchen's construction would require.[11]

Intrinsic Evidence: The intrinsic evidence supports AstraZeneca's construction. Claim 1 of the '085 Patent reads: "The magnesium salt of S-omeprazole trihydrate, wherein the compound is characterized by the following major peaks in its X-ray diffractogram: [d-value / Å and intensity peak list]." Andersen Decl., Ex. 10, col.10 ll.15–33. Representative claim 1 of the '085 Patent and claim 3 of the '466 Patent, and Table 1 of both patents provide peak positions

[11] Indeed, the diffractogram may also have more peaks than those listed in the claims at issue.

and intensities describing a specific form of S-omeprazole magnesium trihydrate. *See, e.g.*, *id.* at col.5 ll.44–60; col.10 ll.20–33. The shared specification provides that the claimed S-omeprazole trihydrate need only "comply" with Table 1, it need not provide a perfect one-to-one correspondence with that reference. *See id.* at col.9 ll.12–13. In other words, the S-omeprazole trihydrate simply must be "identifiable" by reference to the peaks listed in the claims at issue.

In contrast to Anchen's rigid construction, which requires the S-omeprazole trihydrate at issue to have all the referenced peaks, the specification indicates that the intensities provided in Table 1 and the claims at issue are "less reliable" than other characterization metrics. *See* Andersen Decl., Ex. 10, col.5 ll.25–30. In addition, while Table 1 provides some "w (weak)" intensity peaks, the patents provide that a weak peak has a "Relative Intensity" of only 1–3% (and thus for any given diffractogram it would be reasonable to expect that certain referenced peaks may not be visible). *Id.* at col.5 ll.25–40. Indeed, the patents also provide that some "additional very weak peaks have been omitted from" Table 1, indicating that the presence or absence of weaker peaks may not be consistent. *Id.* Thus, while the S-omeprazole trihydrate at issue should be "identifiable by reference" to a diffractogram including the listed peaks, it does not necessarily have to exhibit all of the listed peaks (as Anchen's construction would require).

Extrinsic Evidence: The skilled person would understand the term "characterize" in accordance with its plain dictionary meaning: a "distinguishing feature or quality." *See* Andersen Decl., Ex. 27, at 192 ("To describe the qualities or peculiarities of; To be a distinguishing trait or mark of"); *id.*, Ex. 28, at 347 ("to mark or distinguish as a characteristic; be a characteristic of"). Furthermore, the Examiner involved in prosecuting the '085 and '466 Patents would understand the claim term "characterized" as it is defined in the Manual of Patent Examining Procedure, which explains that "the transitional term . . . 'characterized by' is

inclusive or open-ended and does not exclude additional, unrecited elements or method steps." Andersen Decl., Ex. 29, at § 2111.03. Plaintiffs' construction, which states that the S-omeprazole trihydrate at issue is "identifiable" by the diffractogram, is in line with these definitions.

4. "represented by FIG. 1" ('070 Patent, Claims 2 and 4; '466 Patent, Claims 2 and 10)

Plaintiffs' Proposed Construction	Anchen's Proposed Construction
represented by Figure 1 of the '070 Patent (or '466 Patent)	having an X-ray powder diffractogram the same as FIG. 1

The claim language "represented by FIG. 1" should be construed to mean "represented by Figure 1" of the patent at issue. Anchen's construction, which requires an X-ray diffractogram "the same as FIG. 1" is inconsistent with the intrinsic evidence, and should be rejected.

Intrinsic Evidence: The claim language "represented by FIG. 1" should be given its plain meaning, and refers to Figure 1 of the '070 and '466 Patents. The diffractogram of Figure 1 contains more information than presented in Table 1 of the shared specification and required by claim 1 of the '085 Patent. *See* Andersen Decl., Ex. 10, col.10 ll.15–33. Thus, claims 2 and 4 of the '070 Patent and claims 2 and 10 of the '466 Patent are further limited to the particular form of "the magnesium salt of S-omeprazole trihydrate" represented by Figure 1 of these patents. The specification, however, makes it clear that "represented by" does not have to mean "the same as." Indeed, the S-omeprazole trihydrate at issue in these claims must "comply" with Figure 1, but does not have to have an X-ray diffractogram that is perfectly identical to FIG. 1 (as Anchen's construction would require). *See* Andersen Decl., Ex. 11, col.9 ll.49–51. Thus, Plaintiffs' claim construction should be adopted.

IV. CONCLUSION

Plaintiffs' claim constructions should be adopted for the reasons discussed above.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on August 30, 2012, a true and correct copy of PLAINTIFFS' OPENING *MARKMAN* SUBMISSION (with accompanying Andersen Declaration and Exhibits 1–30; Byrn Declaration and Exhibits A–G; Johnson Declaration and Exhibits A–B; and Williams Declaration and Exhibits A–D) was caused to be served on the below listed counsel of record:

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